STANDARD OPERATING PROCEDURES
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI
INSTITUTE ETHICS COMMITTEE

Responsibility:
To ensure that the research projects that are carried out at All India Institute of Medical Sciences
• Are sound in design, have statistical validity and are conducted according to the Indian Council of Medical Research and International Conference on
• Harmonisation/Good Clinical Practice guidelines
  Do not compromise right, safety and benefits of the patients or volunteers/ study participants.
• Are conducted under the supervision of trained medical / bio-medical persons with the required expertise
• Include, solely, patients or participant who have given voluntary and informed consent
• It may be ensured that no research project shall be / can be started unless Ethics Clearance /
• Approval is obtained and that no retrospective / post facto Ethics Clearance/ Approval can be
• provided to research projects which were neither submitted nor wetted by the Institute Ethics Committee.

The committee expects from the investigators:
• A progress report on six monthly basis or more frequently as the committee feels it.

All serious adverse events observed during conduct of the study should be reported with all the details to the Institute Ethics Committee within twenty four hours and should be reported within ten days to The Drugs Controller General(India), Directorate General of Health Services, Central Drugs Standard Control Organization, New Delhi.*
• To keep informed of amendments to any study related documents
• To keep informed of study discontinuation with reasons.

*THE GAZETTE OF INDIA : EXTRA ORDINARY PART II – Sec. 30(i) page no. 10

Composition:
The Institute Ethics Committee consists of 15 members
• 10 members are from inside All India Institute of Medical Sciences
• 5 members are from outside All India Institute of Medical Sciences
• Out of 15 members 2 members are ladies

These members are as follows:
a) Outside All India Institute of Medical Sciences
1. Dr. T.P. Singh, Chairman
   Research Professor, Clinician
   Deptt. of Distinguished Biotechnology, New Delhi
   Tel. No. 0120-2970172
   Mobile No. 09312249508,09953830047
   Email Id: tpsingh.aiims@gmail.com

2. Dr. Arun Agarwal, Member
Ex-Dean
Professor of Excellence
Department of ENT
Maulana Azad Medical College
President Delhi Medical Council
President Delhi Council of Physiotherapy and Occupational Therapy
R/o – N-9, Green Park Main, New Delhi-110016
Mobile No. 9868252828
Email Id: arunmamce@gmail.com

3. Dr. D.R. Saini, M.A Phd., M.ED,L.L.B.  
Member-Institute Ethics Committee
Principal DPS School, R.K. Puram Sector-12, New Delhi
Mobile No. 9811047905
Email Id: saini.dr@gmail.com

4. Mr. Rajan Khoshla, L.L.B.  
Member-Legal Person
1706-A, B-1, Vasant Kunj, New Delhi-110070.
Off. Tel. No.- 011-26124496
Mobile No. 9868122962, 9013698963
Email - rajankhosla1@gmail.com

5. Prof. Rama V. Baru  
Member-Institute Ethics Committee
Professor
Centre of Social Medicine and Community Health
Social Sciences, JNU
R/o D-44, 3rd Floor, Panchsheel Enclave, New Delhi-17
Off. Phone-26704489
Mobile No. 9810736365
Email - rama.v.baru@gmail.com
Web Address- http://www.jnu.ac.in

b) Inside All India Institute of Medical Sciences

1. Dr. Sunesh Kumar  
Member Professor
Clinician
Dept. of Obst. & Gynae
AIIMS, New Delhi-29
Tel. No. 26594592
Email- kumar.sunesh@yahoo.com

2. Dr. Ramanjitsihota,  
Member Professor
Clinician
Dept. of R.P. Centre,
AIIMS, New Delhi-29
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Mobile No. 9868398455
Email: rjsihota@gmail.com
3. Dr. S.K. Maulik, MD PhD  
   Professor  
   Department of Pharmacology  
   All India Institute of Medical Sciences  
   New Delhi 110029  
   India  
   Tel: Off 0091 11 26593540  
   Mobile: 0091 9958318973  
   Email Id: skmalik@gmail.com

4. Prof. Nikhil Tandon, MD, Ph.D(cantab), FNASc  
   Member, Prof&Head Deptt. of Endocrinology  
   AIIMS, New Delhi  
   Telephone No.-26593433  
   Mobile No.-9868397601  
   Email Id: Nikhil_tandon@hotmail.com

5. Dr. Peush Sahni, MS, Mch.  
   Member-Institute Ethics committee  
   Editor  
   National Medical Journal of India  
   Professor & Head of the Deptt. of GI Surgery and Liver Transplantation  
   AIIMS, New Delhi  
   Telephone No.-26593461  
   Fax No. 01126588663  
   Email Id: peush_sahni@hotmail.com

6. Prof. S.K. Kabra  
   Member-Institute Ethics committee  
   Professor, Deptt. of Paedtrics, AIIMS, New Delhi  
   Telephone No.-26594610  
   Email Id: skkabra@hotmail.com

7. Prof. R.M. PANDEY, Ph.D., DPS, FRSS (UK), FSMS  
   Member  
   Professor & Head  
   Department of Biostatistics  
   All India Institute of Medical Sciences (AIIMS)  
   Ansari Nagar, New Delhi 110029 INDIA  
   Phone:91-011-26593240/26593395  
   Fax:91-011-25598663  
   Mobile:09811912117  
   Email Id: rmpandey@yahoo.com

8. DrVirinder Kumar Bansal  
   Member  
   Additional Professor of Surgery  
   Consultant General, Laparoscopic and Renal Transplant Surgeon  
   Department of Surgical Disciplines, AIIMS  
   Room No. 5021, 5th Floor, Teaching Block  
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   Phone:Resi:+91-11-26262700  
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   Office: +91-11-26593686  
   Fax:+91-11-26588324
If a member is unable to attend a meeting his/her opinion on the project on the agenda maybe submitted in writing to the Chairperson of the Committee before the date of the meeting or decision. The decision of the committee is taken by majority vote. If Chairperson is absent he/she can nominate a person from the Institute Ethics Committee to chair.

**Procedures:**

A quorum is required for all meetings (7 members out of 15 make a quorum). Approval of a project is made by consensus of members present at the meeting. The members can voluntarily withdraw from membership of Institute Ethics Committee after giving due justification and permission of appointing authority. In case a member is absent from Institute Ethics Committee meeting, the following is considered: Since the projects are circulated prior to two weeks of Institute Ethics Committee meeting, if no objection / comments are obtained from that member, they are considered to be approved by that member. Serious Adverse Effects should be reported to Institute Ethics Committee within 24 hours and to DCGI within 10 working days. Efforts are made to ensure that individuals or communities invited for research are selected in such a way that the burdens and benefits of the research are equally distributed. These vulnerable populations include:

a. Racial inequalities
b. Economically or socially disadvantaged
c. Mentally challenged and mentally differently able persons with reduced autonomy (prisoners, students, subordinates, employees, service personnel)

After three years, some new members who have been earlier trained in research methodology workshop are appointed while retaining some older members for guiding them by their hands-on-training in Ethics Committee.

All applicants have to give an undertaking declaring their conflict of interest. Regarding projects from members of Institute Ethics Committee, these members should voluntarily withdraw from the Institute Ethics Committee meeting while making a decision on that project which evokes a Conflict of Interest. This may be indicated to the Chairperson prior to the review and be recorded so in the minutes. (All members shall sign a declaration on conflict of interest).
The chairman appoints a member to write the minutes of the meetings: It is the Member-Secretary who writes the minutes. Minutes are circulated to the Chairperson and after his approval, the comment letters to applicants may be dispatched after the signature of Member-Secretary of the Institute Ethics Committee. After the meeting, the approval of the members of the Institute Ethics Committees obtained on the same day of the meeting. In order to streamline the work of Institute Ethics Committee, an Institute Ethics Committee for Post Graduates Research been formed to assist in evaluation of ethical angles of the MBBS / M.Sc./ M.Biotech/MD/MS/MHA/DM/M.Ch./Ph.D thesis/dissertation. The applicant of a proposal is required to submit 01 copy of his / her application letter and upload the research protocol on IEC software portal(http://14.139.245.45:8082/) with these following documents:

1) Research Protocol
2) Information as desired in the “Format for Submission”
3) Investigator’s Brochure
4) Participant Informed consent form and Participant information sheet in English and translated language in a simple layman’s language, in a narrative form directed to Participant/LAR, covering all the points given on the website
5) Any other project – specific document.
6) Certificate that no work has started.
7) Certificate that work will be done as per Indian Council of Medical Research/Good Clinical Practice guidelines
8) Permission to use copyrighted questionnaire and proforma
9) Updated brief Curriculum Vitae of Principal Investigators

The schedules of submitting the proposal is as follows:

Submissions will be received on all days. Proposals received till 15th of any month will be processed in the coming Institute Ethics Committee meeting and those received after 15th will be processed in the next Institute Ethics Committee meeting. All meetings of Institute Ethics Committee will be held as far as possible on 1st week of every month of January, February, March, April, May, June, July, August, September, October, November and December and those of Institute Ethics Committee for Post Graduates Research on the immediately preceding of the above dates.

The committee will give its opinion on the project in writing in one of the following ways:

Approval
Disapproval
Modification before approval
Discontinuation of previously approved project

The Chairperson / Member-Secretary of the committee may provisionally approve without calling a full meeting in case where only administrative amendment has been made / expedited review is required. This decision will be ratified at the next full committee meeting and minuted. All documents pertaining to the Institute Ethics Committee will be held in the office of the Member-Secretary of Institute Ethics Committee. Members voluntarily withdraw from the Institute Ethics Committee meeting while making a decision on an application which evokes a conflict of Interest which may be indicated in writing to the Chairman prior to the review and be recorded so the minutes. All members shall sign a declaration on conflict of interest.
Serious Adverse Response should be submitted to Contract Research Organisation / Institute Ethics Committee within twenty four hours. In order to assist the Institute Ethics Committee for monitoring of adverse events in clinical trials, a Sub-committee has been constituted vide Memorandum no. F.20-29/2013-Estt.-I dated 09.01.2014. Its function includes giving opinion on causality of Serious Adverse Events and also decide the amount of compensation to be given to the patients with trial related injury along with monitoring of clinical trials. The sub Committee will convey its recommendation to the Institute Ethics Committee which will inform the DCGI its decision about the casualty and compensation regarding the serious adverse events.

This Standard Operating Procedure is effective w.e.f. 01.10.2015

(Dr. Pramod Kumar Garg)
Member-Secretary
Institute Ethics Committee